

supplements may be otherwise exposed to such products, those toxic materials may come in contact with the dietary ingredients or dietary supplements and thereby contaminate them. In addition, clearly identifying the containers in which such toxic materials are held will prevent accidental use.

One comment to the ANPRM objected to the provision in the industry outline that would require manufacturers to register and use rodenticides, insecticides, and fungicides in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act and to follow all relevant Federal, State, and local government requirements. The comment said the requirement would be redundant with other regulations.

Although this CGMP proposed rule does not propose a requirement that you follow all relevant Federal, State, and local government requirements when applying, using, or holding toxic cleaning compounds, sanitizing agents, and pesticides, the proposed rule does not relieve you from such obligations.

Proposed § 111.15(c) pertains to pests. Proposed § 111.15(c)(1) would require that you exclude animals or pests from all areas of your physical plant, while proposed § 111.15(c)(2) would require that you take effective measures to exclude pests from your physical plant and to protect against the contamination of components, dietary ingredients, dietary supplements, or contact surfaces. Therefore, if you have pests in your physical plant, you must take immediate action to get rid of them. In addition, you must take measures to prevent those and any other type of pests from entering your physical plant.

You should note that, like § 110.35(d), proposed § 111.15(c)(1) would allow guard dogs and guide dogs in your physical plant if their presence will not result in the contamination of components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.15(c)(3) would require that you not use insecticides, fumigants, fungicides, or rodenticides unless you take precautions to protect against contamination of your components, dietary ingredients, dietary supplements, or contact surfaces. For example, some pesticides may cause adverse effects in humans, so you must take precautions to ensure that any pesticides you use will not contaminate your components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.15(d) would apply to water supplies and is patterned after the food CGMP requirement at § 110.37(a). Proposed § 111.15(d)(1) would require that you provide water that is “safe and

of adequate sanitary quality,” at suitable temperatures and under pressure as needed in all areas where water is necessary for:

- Manufacturing dietary ingredients or dietary supplements;
- Making ice that comes into contact with components, dietary ingredients, dietary supplements, or contact surfaces;
- Cleaning surfaces; and
- Employee bathrooms and hand washing facilities.

Proposed § 111.15(d)(2) would require that water that contacts components, dietary ingredients, dietary supplements, or any contact surfaces, at a minimum, comply with the National Primary Drinking Water (NPDW) regulations prescribed by the Environmental Protection Agency (EPA) and any State and local government requirements. (EPA’s NPDW regulations can be found at 40 CFR part 141.)

Proposed § 111.15(d) would require that you use water that is of safe and sanitary quality in all aspects of your operation where, if such water was not used, could result in contamination and adulteration of your dietary ingredients and dietary supplements. Further, under proposed § 111.15(d)(2), in any operation where water contacts components, dietary ingredients, dietary supplements or any contact surfaces, the water must comply with the EPA’s NPDW regulations. We believe that the EPA’s NPDW water regulations are necessary because contaminated water can contaminate dietary ingredients and dietary supplements both when used as an ingredient in the dietary ingredient or dietary supplement and when contaminated water is allowed to enter the product indirectly, as can occur, for example, when water is used to cool a product or to clean a contact surface.

We recognize that, for some operations, you may want to use water that is more pure or of higher quality than that required under the NPDW regulations. For example, to ensure the purity of your dietary supplements, you might use water that has gone through water purification and filtering equipment to ensure that the water is clean and sterile. In contrast, to clean contact surfaces and other surfaces, sterilized water may be unnecessary because a contact surface that is exposed to the environment will not remain sterile; airborne microorganisms and microorganisms on your employees will find their way onto the contact surface, thereby rendering it nonsterile. Proposed § 111.15(d) would not prevent you from using water that is more pure than that required under the NPDW

regulations. Proposed § 111.15(d) provides you with the flexibility to raise your water quality above the minimum criteria to meet your particular manufacturing needs. We acknowledge that foreign firms may not be subject to EPA water requirements or adhere to EPA requirements. Nevertheless, water quality is an important part of CGMPs, so we invite comment on our proposed requirement that does not distinguish between foreign or domestic requirements, and, therefore, would require foreign firms to meet the NPDW regulations.

A number of comments to the ANPRM suggested that we should require the use of potable water (water that is fit to drink) or a higher quality water or establish potable water as the minimum quality water standard. One comment stated that the industry outline, by referring to potable water, prevents the use of water whose quality exceeded a potable water standard because a higher quality water would not be in compliance.

We agree that potable water should be a minimum water quality standard, and proposed § 111.15(d) would reflect that standard. Proposed § 111.15(d)(1) would require water to be “safe and of adequate sanitary quality.” Water that is “safe and of adequate sanitary quality” is or should be potable. Proposed § 111.15(d)(2) would require water that contacts components, dietary ingredients, dietary supplements, or contact surfaces to meet, at a minimum, EPA’s NPDW regulations and State and local requirements. Water meeting these requirements is potable.

Please note that proposed § 111.15(d) does not prevent you from using water that is more pure or of higher quality than that required under EPA’s NPDW regulations. We reiterate that proposed § 111.15(d) would establish minimum water quality standards.

Proposed § 111.15(d) does not make any distinctions between water from public sources and water from private sources. Consequently, if you use water from private sources, you would need to ensure that the water meets the minimum water quality standards in proposed § 111.15(d). For example, if you use a well as your water source, you would need to ensure that the well design meets government water quality standards and you may need to perform appropriate water treatment procedures, including filtration, sedimentation, and chlorination. These actions are necessary because private water sources, such as surface waters or water from shallow wells, may be subject to microbiological, chemical, or radiological contamination. For